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Area	Governance Policies

Duty of Candour & Being Open

1. Introduction

The effects of harming a person can have severe emotional and physical consequences for the person, their families, and their carers, as well as potentially being distressing for the professionals involved.

Being transparent about events and having open and honest conversations in a timely manner can help all those individuals involved cope better with the aftereffects of harmful events.

Remember: saying sorry is not an admission of liability and is the right thing to do.

The principles of being open are embedded in the NHS Constitution for England and supported by professional and indemnity bodies.
It is a legal requirement to fulfil the Duty of Candour process where applicable. The full regulation can be viewed on the CQC website.

2. Scope

This policy applies to:

- All colleagues working within the GPCG, including self-employed contractors, locum and agency workforce.
- Incidents that occur on any of the premises, including all people who use the service, employees, visitors, or contractors.
- Incidents involving employees or service users that occur in any other setting, when an employee is carrying out their duties.

This GPCG statuatory 'Duty of Candour' policy only relates to those incidents where harm, suffering (see definition below) or possible future harm could occur and the consequences are graded as moderate, major (referred to as 'severe' in the NPSA framework) or catastrophic (referred to as 'death' in the NPSA framework). Implementation of this policy will be an integral part of the management and investigation of these incidents. However, there is flexibility to discuss incidents resulting in a lower level of harm (including

no harm) with the person affected on an individual basis depending on local circumstances and the best interest of the person. Where this does occur details of all communication must be documented within 'Openness & Transparency' within Datix (see Appendix A) and the persons care records, including uploading any letters of correspondence.

3. Purpose

This policy provides guidance on how to embed the Duty of Candour Policy and details the process to ensure that the Duty of Candour requirements are fulfilled and a framework to support colleagues to have the confidence to act appropriately when things go wrong. The Policy also offers guidance on communication with people affected.

This guidance should be used when any event occurs whether as a result of a complaint or an adverse incident.

4. Definitions

Apology: A sincere expression of regret offered for harm sustained.

Being Open: Open communication of events (adverse incidents, complaints or claims) that result in harm or death of a patient whilst receiving healthcare.

Claim:

- **Clinical claim**: A claim for compensation in respect of adverse clinical incidents, which led to personal injury.
- **Employer's liability**: Claims for compensation for injury or ill health to colleagues arising out of work.
- **Public liability**: claims for injuries to members of the public (including patients) following an accident on GPCG property.

Complaint: An expression of dissatisfaction by one or more members of the public about the GPCG's action or lack of action, or about the standard of a service, whether the action was taken by the GPCG itself or by somebody acting on behalf of the GPCG.

Duty of Candour: A statutory requirement to undertake volunteering all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made.

Harm: Injury (physical or physiological), disease, suffering, disability or death.

Injury: Damage to tissues caused by an agent or circumstance.

Moderate harm: Harm that requires a moderate increase in treatment and significant, but not permanent, harm.

Moderate increase in treatment: An unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care)

Near misses: The intention of the term "could result in harm" in the harm definitions is not to bring near

misses into scope as notifiable safety incidents. It is designed to reflect harm that is not apparent at the time of the incident but that may appear later.

'Never Event': Defined as 'serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers.

Patient safety incident: Any unintended or unexpected incident that could have or did lead to harm of any patient receiving healthcare within the GPCG.

Patient Safety Incident Investigation (PSII) A patient safety incident investigation is undertaken when an incident or near-miss indicates significant patient safety risks and potential for new learning

Patient Safety Incident Response Framework (PSIRF) a framework that allows for learning and improvement emphasising the system and culture to make that improvement sustained and keep our patients and service users safer.

Prolonged pain: Pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Prolonged psychological harm: Psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Possible Future Harm: Where the person could be subject to harm in the future as a result of the incident.

Root cause analysis (RCA): A systematic approach in which contributing factors to any event are identified, and in which understanding of the underlying causes and environmental context of the event is sought.

Severe harm: A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

Suffering: Experiencing anything subjectively unpleasant. This may include pain, malaise, nausea and/ vomiting, loss, depressions, agitation, alarm, fear, grief or humiliation.

5. Roles & Responsibilities

All colleagues are responsible for reporting safety incidents on the Datix incident reporting system on the investigation page (DIF2) of the datix form (Appendix A). Documenting any conversation with the person and any other relevant people relating to the reported incident in the persons' health record.

Clinical Leads (or Service Leads) are responsible for providing an apology to the person affected following a reported notifiable incident according to the principles of the Duty of Candour. Documenting any conversation with the people involved relating to the reported incident in the person's health record. Providing a written notification to the person or other relevant people in conjunction with the support and sign off from the most relevant Executive Director.

The Chief Medical Officer(s) have over all accountability ensuring the strategic implementation of this policy.

The Associate Director of Governance and Lead Nurse has responsibility for providing advice to senior colleagues and ensuring operational implementation of this policy across the GPCG. The Associate Director of Governance and Lead Nurse is responsible for ensuring any appropriate bodies have been notified or informed as per the incidents policy, identifying Duty of Candour has been upheld.

Service & clinical leads have responsibility for fostering a culture of learning within team and ensuring that the Duty of Candour requirements are appropriately implemented. They are also responsible for reporting on the outcomes and any learning as a result of the process. Leads have the responsibility of auditing their service compliance in relation to adherence to the GPCG Duty of Candor policy.

6. Process

Event recognition and detection

The Duty of Candour process starts with the recognition that a person has suffered harm, possible harm or has died as a result of an unexpected event or omission in the course of their care. The first priorities once an event is identified are:

To ensure that the individual is safe and has since received timely and appropriate clinical care.

To prevent any further harm, either to the individual or to others who may be at risk.

If the incident is considered to have caused moderate or severe harm (please refer to the GPCG PSIRF Policy) or caused the death of a person it will be subject to the Duty of Candour requirements.

Incidents are almost always unintentional, however if at any stage it is determined that the harm may have been the result of a criminal or intentionally unsafe act the Chief Medical Officer, or in their absence, the Executive on call must be notified by telephone immediately.

CQC Flow chart for deciding on Duty of Candour (CQC 2022)

Communication with patients, their families or carers

The role and seniority of the person given the role of communication will depend on the severity of the situation. The decision should be reached considering the following:

- They should, wherever possible, be known to and trusted by the affected individuals.
- They must have a good understanding of the facts relevant to the situation.
- They must have enough experience and expertise to be credible to the patient or family members.
- They should have excellent interpersonal skills and be able to communicate in ways that can be easily understood.
- They must be willing to offer a meaningful apology, provide reassurance and feedback.
- They must be able to maintain a long-term professional relationship with the person, their family or carer if required.

If the appropriate senior healthcare professional is unavailable, advice should be sought from the Service Lead and Associate Director of Governance and Lead Nurse, or the Executive lead on call.

Some events will have been as a result of an error made by healthcare colleagues who may wish to participate in the Duty of Candour discussion to apologise personally, they should be supported to do so by their colleagues. If a colleague does not wish to do so, consideration should be given to providing a written apology to the person during the initial discussion.

Clear records of cases should be maintained where you have responded to notifiable safety incidents. It may be that the incident is a serious incident and also meets the notification thresholds. If so, should be reported through an Executive lead to the CCG and CQC.

If the relevant person involved cannot be, or refuses to be, contacted, you must keep a written record of all attempts to make contact. You must still report the incident through the appropriate notifications system and investigate it in order to prevent harm occurring to others.

The Initial Duty of Candour Discussion

The initial discussion should take place as soon as possible after the recognition of the event. It is the first part of an ongoing communication process. Where moderate or severe harm is deemed to have occurred this must take place within 10 working days of the event being recognised to satisfy Duty of Candour regulations. This should be verbal or face to face wherever possible.

The timing of the meeting should take into account:

- Condition of patient
- Patient preference in terms of location, timing and healthcare professionals involved
- Privacy and comfort for the patient
- Availability of patient's family or carer
- Availability of key senior colleagues

First Meeting

The regulation states that you must:

1. Tell the relevant person, preferably face-to-face, that an incident has taken place.
2. Apologise
3. Provide a true account of what happened, explaining whatever you know at that point and what this means to the person.
4. Explain to the relevant person what further enquiries or investigations you believe to be appropriate and what learning has taken place.
5. Ask the person involved, if they have have questions that they would like answered.
6. For incidents resulting in suffering, moderate-severe harm or if an investigation has taken place, follow up by providing this information and the apology, in writing.
7. Document the correspondence in datix on the investigation page of the incident report form and their health records, uploading any written correspondence.

The purpose of these meetings and communications is to share whatever is known about the incident truthfully, openly and with compassion and support. The person who was harmed has a right to understand what has happened to them. The meeting is not about trying to apportion blame, and in any case, it is likely

that investigations will still be underway at this point.

7. Monitoring Compliance

Compliance with this policy will be monitored via monthly analysis of incident data and outcomes in the datix system. Service audits of Duty Of Candour will review compliance with timeframes and notification requirements and review outcomes for learning.

Appendix A Examples

The CQC regulation also defines 'notifiable safety incidents' and specifies how registered persons must apply the duty of candour if these incidents occur.

Examples of notifiable safety incidents

It is impossible to cover all the possible events and circumstances that may or may not qualify as notifiable safety incidents.
These case studies provide examples of how to apply the criteria.

Example 1: General Practice

What happened

A young man fell over while playing badminton and goes to his GP the next day with a swollen and painful foot and ankle. His GP decides not to order an x-ray and sends him home with advice to rest, ice, compress and elevate the leg. He tells the man he can weight bear fully. Over the following week, the pain and swelling does not improve, and the man goes back to the GP surgery and sees a different doctor who sends him for an x-ray. He is found to have a fracture of the base of fifth metatarsal that should have been put into a plaster cast and should have been non-weight bearing. Due to this mismanagement, the patient develops a non-union over the following six weeks which causes him ongoing pain and eventually requires surgical intervention in hospital.

Does this qualify as a notifiable safety incident?

1. Was the incident unexpected or unintended?
   Yes. The incident was both unexpected and unintended.
2. Did it occur during provision of a regulated activity?
   Yes. It occurred during provision of the regulated activity 'treatment of disease, disorder or injury'.
3. Has it resulted in death or severe or moderate harm?
   Yes. The incident resulted in prolonged pain, impairment of motor functions, and the need for surgical intervention. The patient was receiving care in a GP surgery so the definitions in Regulation 20(9) apply.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident.
And all steps outlined in the duty of candour (Regulation 20) should be carried out.

Example 2: Maternity

What happened

A woman in an NHS hospital experienced pain during an elective caesarean section. She found this experience traumatic and subsequently had an acute episode of severe anxiety and depression that lasted more than 28 days. It was discovered that she had been not receiving enough anaesthesia from an epidural line.

Does this qualify as a notifiable safety incident?

1. Was the incident unexpected or unintended?
   Yes. The incident was both unexpected and unintended.
2. Did it occur during provision of a regulated activity?
   Yes. The incident occurred while the woman was receiving care under the regulated activity 'maternity and midwifery services'.
3. Has it resulted in death or severe or moderate harm?
   Yes. The incident has resulted in "prolonged psychological harm" (psychological harm lasting more than 28 days). The woman was receiving care in an NHS hospital so the harm definitions in Regulation 20(8) apply. If the maternity care had been delivered in an independent hospital, Regulation 20(9) would apply instead.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident.
And all steps outlined in the Duty of Candour (Regulation 20) should be carried out.

Example 3: Care home

What happened

An occupational therapist completed an assessment with a care home resident whose mobility was deteriorating. They advised that grab rails were needed in his bathroom before it was safe for him to use the bath, and that in the meantime colleagues should assist him with a wash each morning. The manager failed to update the man's care plan or inform the care colleagues of this change, so colleagues supported him to take a bath the following morning as usual. He slipped when getting out of the bath and broke his arm. The arm was put in a plaster cast and the man needed full assistance for all aspects of his care for six weeks until the cast was removed. He made a full recovery.

Does this qualify as a notifiable safety incident?

1. Was the incident unexpected or unintended?
   Yes. The incident may not be unexpected, but it is unintended.
2. Did it occur during provision of a regulated activity?
   Yes. The incident occurred during the provision of the regulated activity accommodation for persons who require nursing or personal care'.
3. Has it resulted in death or severe or moderate harm?
   Yes. The injury in this case is a broken arm and would fall under Regulation 20(9)(b)(ii) as if the injury was left untreated the person using the service could experience one or more of the

scenarios referred to in Regulation 20(9)(a)(i) to (v). The person was receiving care in a care home so the definitions in section 9 rather than 8 apply.

Conclusion

The answers to all three questions are 'yes'. So, this qualifies as a notifiable safety incident.
And all steps outlined in the Duty of Candour (Regulation 20) should be carried out.

Example 4: Surgery

What happened

An elderly woman undergoes a coronary artery bypass operation. She has given appropriate consent for the risks of the operation, including for stroke and death. Unfortunately, the woman suffers a large stroke during the operation and dies as a result.

Does this qualify as a notifiable safety incident?

1. Was the incident unexpected or unintended?
   Yes. The incident was a possible risk of the operation, and as such her consent was sought; however the incident was still unintended.
2. Did it occur during provision of a regulated activity?
   Yes. The incident occurred during provision of the regulated activity 'Surgical procedures'.
3. Has it resulted in death or severe or moderate harm?
   Yes. The incident resulted in death. The woman was receiving care in an NHS hospital so the definitions in Regulation 20(8) apply. The incident resulted in death.

Conclusion

The answers to all three questions are 'yes'. So, this qualifies as a notifiable safety incident. And all steps outlined in the Duty of Candour (Regulation 20) should be carried out. Note that on the facts provided in this example, there is no suggestion of error or fault on the part of the provider. But neither is required for something to qualify as a notifiable safety incident.

Example 5: Mental health

What happened

A prescribing error on a mental health ward resulted in a detained patient being given double her normal dose of lithium for several days. She developed lithium toxicity, which required inpatient admission. She made a full recovery.

Does this qualify as a notifiable safety incident?

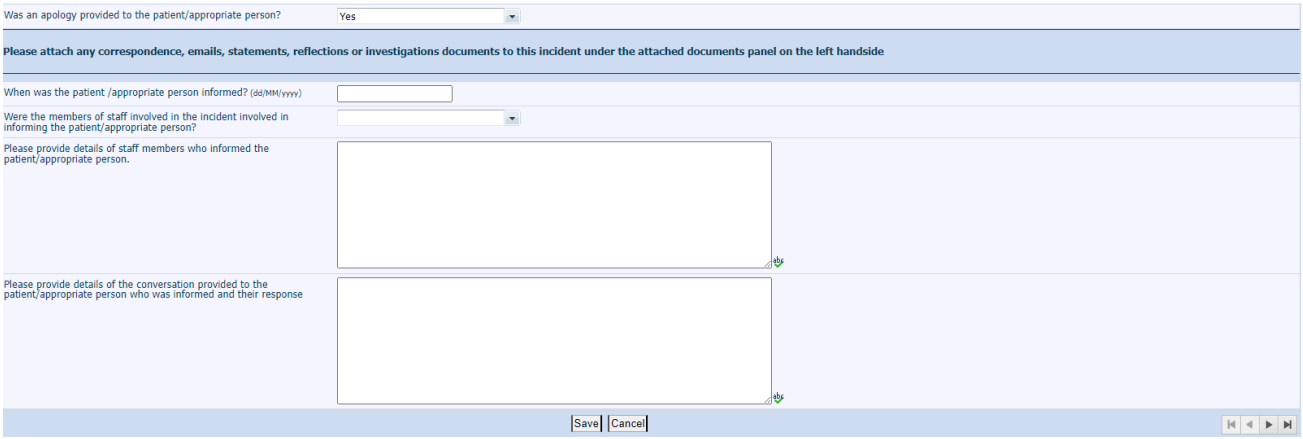
1. Was the incident unexpected or unintended?
   Yes. The incident was both unexpected and unintended.
2. Did it occur during provision of a regulated activity?
   Yes. It occurred during provision of the regulated activity 'assessment or medical treatment for persons detained under the Mental Health Act 1983'.
3. Has it resulted in death or severe or moderate harm?
   Yes. The incident resulted in moderate harm as defined in 20(7) (significant, but not permanent,

harm, and a moderate increase in treatment). The patient was receiving care in an NHS trust so the definitions in Regulation 20(8) apply.

Conclusion

The answers to all three questions are 'yes'. So, this qualifies as a notifiable safety incident. And all steps outlined in the Duty of Candour (Regulation 20) should be carried out.

Appendix A
Datix Apology and Duty of Candour section



Attachments

Image 2

Approval Signatures

Step Description	Approver	Date